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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/092,296	06/05/98	BILLING-MEDEL	F 6104.US.01

HM12/1227

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EXAMINER	
NICKOL,G	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/27/00

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/092,296	Applicant(s) BILLING-MEDEL ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11,12,14 and 16-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11,12,14 and 16-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Response to Amendment

The Amendment filed February 15, 2000 (Paper No. 12) in response to the Office Action of November 08, 1999 is acknowledged and has been entered. Claims 1-6, 11-12, 14, and 16-33 are pending. Claims 1, 5, 12, and 14 were amended. New Claim 34 was added. Claims 1-6, 11-12, 14, and 16-34 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The specification on page 1 should be amended to reflect the priority status of the present application, for example:

This application claims benefit to provisional application 60/048810, filed June 5, 1997, now abandoned.

The specification is objected to on page 8, line 30 for a syntax error following the word "image".

The use of trademarks such as REDICOL disclosed on page 61, line 34, of the specification has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Each letter of the trademarks must be capitalized. See MPEP 608.01(V) and Appendix I. Appropriate corrections are required.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-6, 11-12, 14, 16-34 of this application. Applicant's argue in Paper No. 12 that new claim 34 is entitled to the provisional date which claims nucleotides 5-419 of SEQ ID NO: 7. This argument has been considered but is not found persuasive. A review of provisional 60/048810 revealed a SEQ ID NO: 7 with only 203 nucleotides. Applicants further argue that SEQ ID NO: 15 is entitled to the provisional date based on an inference from the previous examiner's failure to raise the objection in the office action of 11-8-99, Paper No. 11. This argument has been considered but is not found persuasive. SEQ ID NO: 15 of the present application is not the same as SEQ ID NO: 15 of provisional 60/048810. Therefore, all pending claims of the present application will receive a priority date of the date of filing, that is, June 5, 1998. If applicant disagrees with any rejection set forth in this office action based on examiner's establishment of a priority date 6-5-98 for the instantly claimed application serial number 09/092,296, applicant is

invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

REJECTIONS MAINTAINED

Claims 1-6, 11-12, 14, 16-18, 22-25, and 30-33 remain rejected and Claims 19-21, and 34 are rejected under 35 U.S.C. 112, first paragraph- for reasons of record in Paper No. 11, pages 9-13, because the specification, while being enabling for a purified polynucleotide consisting of SEQ ID NOs: 1-3, vectors consisting of SEQ ID NOs: 1-3, and nucleotides 51-284 of SEQ ID NO: 7, does not reasonably provide enablement for the various polynucleotides and vectors with 50% identity to SEQ ID NOs: 1-3 and nucleotides 51-284 of SEQ ID NO: 7 and or nucleic acid sequences encoding at least one epitope, various fragments, and complements thereof.

Applicant's argue in Paper No. 12, page 6, that the amendments to the claims render the rejection moot wherein "specifically binds" language was removed. This argument has been considered but is not found persuasive for the reasons of record in Paper No. 11, pages 9-13. Applicant is **only** enabled for the following: a purified polynucleotide of SEQ ID NO: 1, 2, or 3, (i.e. see claim 26) a purified polynucleotide which is the complete complement of SEQ ID NO: 1, 2, or 3, an expression vector consisting of SEQ ID NO: 1, 2, or 3, and a cell transfected with the expression vector for the reasons of record in Paper No. 11, pages 9-13. Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1-4,12, 22-25, and 30-33 remain rejected under 35 USC 102(b) as being anticipated by Adams et al. (Nature, 377:3-174, 1995) for reasons of record in Paper No. 11, pages 13-15. Applicant argues in Paper No. 12, page 7, that the claims, as amended, cover full complements, not partial complements. This argument has been considered but is not found persuasive for reasons of record in Paper No. 11, pages 13-15. The, claims as amended, remain inclusive to *any* naturally occurring polynucleotide sequence with 50% similarity to the claimed sequences.

Claims 1-4, 12, 22-25, and 30-33 remain rejected under 35 USC 102(e) as being anticipated by Kuroda et al. (US Patent 5, 773,688, filed April, 1995) for reasons of record in Paper No. 11, page 15. Applicant argues in Paper No. 12, page 8, that Kuroda et al. only teach a small segment of SEQ ID NO: 2, not the entire sequence encompassed by the claim. This argument has been considered but is not found persuasive for reasons of record in Paper No. 11, pages 13-15. The, claims as amended, remain inclusive to *any* naturally occurring polynucleotide sequence with 50% similarity to the claimed sequences.

NEW REJECTIONS/OBJECTIONS

Claim Objections

Claim 34 is objected to because of the following informalities: "of" is misspelled. Appropriate correction is required.

Claim 14 is objected to because it appears that a word is missing between "50%" and "to".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 11-12, 14, and 16-34 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are drawn to a purified polynucleotide that comprises a polynucleotide which has at least 50% identity to a polynucleotide sequence selected from the group consisting of SEQ ID NO: 1, 2, and 3, and full complements thereof. The claims are further drawn to a recombinant expression vector for use in desired host comprising a nucleic acid sequence that encodes an open reading frame of at least 5 amino acids, said nucleic acid sequence having at least 50% identity with a polynucleotide selected from the group consisting of SEQ ID NO: 1, 2, and 3, and nucleotides 51-284 of SEQ ID NO: 7. The claims are further drawn to a cell transfected with a nucleic acid sequence encoding one epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO: 1, 2, and 3, fragments comprising at least about 10 nucleotides of any of SEQ ID NO: 1, 2, and 3 and complements thereof. The claims are further drawn to a purified polynucleotide or a fragment thereof which codes for a protein which comprises an amino acid sequence having at least 50% identity to SEQ ID NO: 15. The claims are further drawn to a cell transfected with a nucleic acid (and/or a purified polynucleotide) encoding at least one epitope of at least 5 amino acids encoded by nucleotides 51-284 of SEQ ID NO: 7. The claims are further drawn to a purified polynucleotide comprising a polynucleotide which has at least 50% identity to nucleotides 5-419 of SEQ ID NO: 7.

The specification teaches that the present invention provides a method of detecting a target LS147 polynucleotide in a test sample with comprises contacting the test sample with at least one LS147-specific polynucleotide and detecting the presence of the target LS147 polynucleotide in the test sample. The specification further teaches that the LS147-specific polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of SEQ ID NOs: 1-7. (page 6, lines 13). Hence, the disclosed utility of the LS147-specific polynucleotides as claimed resides in their being a specific asserted utility or a well established utility for LS147. However, neither the specification nor any art of record teaches what the LS147 polynucleotide is, how it functions, or a specific and well-established utility for any of the fragments claimed. Furthermore, the specification does not teach a relationship to any specific disease or establish any involvement in the etiology of any specific disease. The specification only teaches that a probe specific for LS147 was detected in a lung sample, but not in eleven non-lung RNA samples (page 65, lines 15-19). Additional disclosed utilities for LS147 include portions of the nucleic acid sequences useful as primers for the reverse transcription of RNA or for the amplification of cDNA; or as probes to determine the presence of certain mRNA sequences in test samples. Also disclosed are nucleic acid sequences which permit the production of encoded polypeptide sequences which are useful as standards or reagents in diagnostic immunoassays, as targets of pharmaceutical screening assays and/or as components or as target sites for various therapies. The specification further teaches that the isolation of sequences of other portions of the gene of interest can be accomplished utilizing probes or PCR primers derived from these nucleic acid sequences. This allows additional probes of the mRNA or cDNA of interest to be established, as well as corresponding encoded polypeptide sequences. These

additional molecules are useful in detecting, diagnosing, staging, monitoring, prognosticating, in vivo imaging, preventing or treating, or determining the predisposition to diseases and conditions of the lung, such as lung cancer, characterized by LS147 (page 12, lines 20-34).

The asserted utility of LS147 and its encoded products (i.e. SEQ ID NO: 15, page 58) is based on the assertion that LS147 is differentially expressed in lung cancer versus normal lung tissue wherein the specification teaches that detection of a product comprising a sequence selected from the group consisting of SEQ ID NO: 1-7, and fragments or complements thereof, is indicative of the presence of LS147 mRNA, *suggesting* a diagnosis of a lung tissue disease or condition, such as lung cancer (page 64, lines 14-17). However, neither the specification nor any art of record teaches what the LS147 polynucleotide is, how it functions, or a specific and well-established utility for any of the fragments claimed. Essentially, evidence that LS147 is expressed in lung tissues does not extrapolate into a substantial utility because there is no evidence that its expression is altered when compared to diseased lung tissues. Further, tissue enrichment of a particular molecule provides neither specific nor substantial utility because it is clear that all polynucleotides are expressed and that, other than housekeeping genes, there is always a pattern of expression of these polynucleotides. Although the specification provides some background into the efforts to discover improved tumor markers for lung cancer wherein a novel gene, N8, was found by differential display to express higher levels of mRNA in lung tumor than in normal lung disease (page 3, line 32), there is no evidence presented that suggest the same properties for LS147 since polynucleotides specific for LS147 only differentiate between lung tissue and completely different tissues.

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polynucleotide, complements and fragments thereof, and encoded products. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 11-12, 14, and 16-34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

If applicant were able to overcome the rejections under 35 USC 101 and USC 112 1st paragraph above, the following claims would still be rejected:

Claim Rejections - 35 USC § 112

Claims 1-4, and 22-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 11-12,14,16-25, 27-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NOs:1, 2 and 3, nucleotides 51-284 of SEQ ID NO: 7, SEQ ID NO: 15, and nucleotides 5-419 of SEQ ID NO: 7. Therefore the written description is not commensurate in scope with the claims drawn to naturally occurring polynucleotide sequences (alternatively, compositions of matter) having 50% identity to a polynucleotide sequence of SEQ ID NO: 1, 2, and 3; vectors comprising a nucleic acid sequence that encodes an open reading frame of at least 5 amino acids, said nucleic acid sequence having at least 50% identity with a polynucleotide selected from the group consisting of SEQ ID NO: 1, 2, 3, and 51-284 of SEQ ID NO: 7, a cell transfected with a nucleic acid sequence encoding at least one epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO: 1, 2, 3, fragments comprising at least about 10 nucleotides of any of SEQ ID NO: 1,2,3, and complements thereof, a purified polynucleotide or a fragment thereof which codes for a protein which comprises an amino acid sequence having at least 50% to SEQ ID NO: 15. The fragments, complements, and sequences encoding open reading frames read on the naturally occurring gene and allelic variants.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined, nor in this case, is the structure of allelic variant proteins encoded by allelic variant genes defined. With the exception of SEQ ID NO:1, 2, or 3, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotide sequences comprising 50% sequence identity to SEQ ID NO:1, 2, and 3, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The sequences themselves are required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

The instant disclosure (page 7, lines 21-32), however, of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within

the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides and encoded polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the 5' and 3' regulatory regions and untranslated regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the full-length gene. The art indicates that the structures of genes with naturally occurring regulatory elements and untranslated regions is empirically determined (Harris et al., J. of The Am Society of Nephrology 6:1125-33, 1995; Ahn et al., Nature Genetics 3(4):283-91, 1993; and Cawthon et al., Genomics 9(3):446-60, 1991). Therefore, the structure of these elements is not conventional in the art, and one skilled in the art would therefore not recognize from the disclosure that applicant was in possession of the genus of nucleic acid, including genes, comprising polynucleotides which encode the amino acids of SEQ ID NO: 2.

Furthermore, although drawn specifically to the DNA art, the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Therefore only an isolated polynucleotide consisting of SEQ ID NOs:1, 2, or 3, full complements thereof, expression vectors consisting of SEQ ID NOs:1,2, 3, or nucleotides 51-284 but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

Claim 34 is rejected under 35 USC 102 (b) as being anticipated by Kubota et al. (Genbank Sequence Database (Accession D86631), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available July 26, 1996.)

The claim is drawn to a purified polynucleotide comprising a polynucleotide which has at least 50% identity to nucleotides 5-419 of SEQ ID NO: 7.

Kubota et al. teach a purified polynucleotide comprising a polynucleotide which has at least 50% identity to nucleotides 5-419 of SEQ ID NO: 7 (see sequence comparison, us-09-092-296-7_5-419).

Claim 14 is rejected under 35 USC 102 (b) as being anticipated by Chen et al. (Genbank Sequence Database (Accession JC5237), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available- March 1997.)

The claim is drawn to a purified polynucleotide, or a fragment thereof, which codes for a protein which comprises an amino acid sequence having at least 50% to SEQ ID NO: 7.

Chen et al. teach a polypeptide fragment (encoded by a purified polynucleotide or fragment thereof- see title) which comprises an amino acid sequence having at least 50% identity to SEQ ID NO: 7.

Claims 5-6, 16-21, and 27-29 are rejected under 35 USC 102 (b) as being anticipated by Bonaldo et al. (Genome Res. Vol. 6, No. 9, pages 791-806, 1996) as evidenced by the attached sequence alignment- accession No.AI136523.

The claims are drawn to a recombinant expression vector for use in a desired host comprising a nucleic acid sequence that encodes an open reading frame of at least 5 amino acids, said nucleic acid sequence having at least 50% identity with a polynucleotide selected from the group consisting of SEQ ID NO: 1, 2, 3, and nucleotides 51-284 of SEQ ID NO: 7, wherein said

open reading frame is operably linked to a control sequence compatible with the desired host wherein said control sequence is selected from the group consisting of promoters, terminators, enhancers, ribosomal binding sites and leader sequences (Claim 5); and a cell transfected with the recombinant expression vector (Claim 6) wherein said open reading frame is at least 8, or 10, or 15 amino acids (Claims 16-18). The claims are further drawn to a cell transfected with a nucleic acid sequence encoding at least one epitope wherein the epitope consists of at least 5 amino acids encoded by the nucleotides 51-284 of SEQ ID NO: 7 (Claim 19); wherein said epitope consists of at least 8 amino acids (Claim 20); wherein said epitope consists of at least 10 amino acids (Claim 21). The claims are further drawn to a purified polynucleotide encoding at least one epitope wherein the epitope consists of at least 5 amino acids encoded by nucleotides 51-284 of SEQ ID NO: 7 (Claim 27); wherein said epitope consists of at least 8 amino acids (Claim 28); wherein said epitope consists of at least 10 amino acids (Claim 29).

Bonaldo et al. teach a recombinant expression vector (pT7T3D-Pac) vector for use in a desired host comprising a nucleic acid sequence that encodes an open reading frame of at least 5 amino acids, said nucleic acid sequence having at least 50% identity with a polynucleotide selected from the group consisting of nucleotides 51-284 of SEQ ID NO: 7, wherein said open reading frame is operably linked to a control sequence compatible with the desired host wherein said control sequence is selected from the group consisting of promoters, terminators, enhancers, ribosomal binding sites and leader sequences (Bonaldo et al. teach a cell (DH10B bacteria) transfected with a nucleic acid sequence encoding at least one epitope wherein the epitope consists of at least 5 amino acids encoded by the nucleotides 51-284 of SEQ ID NO: 7 wherein said epitope consists of at least 8 amino acids; wherein said epitope consists of at least 10 amino

acids. Bonaldo et al. further teach a a purified polynucleotide encoding at least one epitope wherein the epitope consists of at least 5 amino acids encoded by nucleotides 51-284 of SEQ ID NO: 7; wherein said epitope consists of at least 8 amino acids; wherein said epitope consists of at least 10 amino acids. Although the reference does not specifically teach the encoded epitopes or open reading frames, the claimed epitopes and open reading frames are an inherent feature in the prior art, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim 11 is rejected under 35 USC 102 (b) as being anticipated by Attie et al. (Genbank Sequence Database (Accession T06957), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available- June 1996.)

The claim is drawn to a cell transfected with a nucleic acid sequence encoding at least one epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO: 1,2, 3, fragments comprising at least about 10 nucleotides of any of SEQ ID NO: 1,2, 3, and complements thereof.

Attie et al. teach a cell transfected with a nucleic acid sequence encoding at least one epitope (The protein encoded would inherently comprise an epitope), wherein said nucleic acid

sequence is selected from the group consisting of SEQ ID NO: 1,2, 3, fragments comprising at least about 10 nucleotides of any of SEQ ID NO: 1,2, 3, and complements thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 22, 2000

SUSAN UNGAR, PH.D
PRIMARY EXAMINER